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10/578,507	05/08/2006	Ritsuko Ehama	AIA-117-PCT	7877

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,507	EHAMA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 Dec 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *5-10, 13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5pgs / 08May2006, 13Sep2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is the national stage entry of PCT/JP04/17037, filed 10 Nov 2004; and claims benefit of foreign priority document JAPAN 2003-381470, filed 11 Nov 2003; currently an English language translation of this foreign priority document has not been filed.

Claims 1-14 are pending in the current application. Claims 5-10, 13 and 14, drawn to non-elected inventions, are withdrawn. Claims 1-4, 11 and 12 are examined on the merits herein.

Election/Restrictions

Applicant's election without traverse of the invention of Group I, claims 1-4, 11 and 12 in the reply filed on 14 Dec 2007 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-10, 13 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 14 Dec 2007.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 4 recite an intended use and an intended result, but no active step for the claimed method. Therefore claims 1 and 4 are drawn to non-statutory subject matter, being an improper definition of a process. See MPEP 2173.05(q)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: an active step of the claimed method. Claims 1 and 4 recite an intended use and an intended result, but no active step for the claimed method. See MPEP 2173.05(q).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-4, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Tajima et al. (US Patent Application Publication US 2002/0192177, published 19 Dec 2002, cited in PTO-892), herein refered to as the '177 PGPub.

The '177 PGPub discloses a hair tonic, or external skin preparation, containing adenosine or adenosine 5'-phosphate as an active ingredient having hair loss preventing action and hair growth promoting action (page 1, paragraph 14-15). The '177 PGPub discloses applying said hair tonic to the scalp of a human subject (page 3, paragraph 54), anticipating instant claims 1-4. By applying said tonic to the scalp, one inherently treats hair follicle cells that are dermal papilla cells or outer root sheath cells, anticipating instant claims 11 and 12. The '177 PGPub does not explicitly state that the biological pathway by which the disclosed method operates is by increasing the expression of keratinoctye growth factor (FGF-7) in hair follicle cells.

Note that "increasing the expression of keratinoctye growth factor (FGF-7) in hair follicle cells" is merely considered to be a new function or the unknown property or mechanism of action of a known treatment, applying said hair tonic to the scalp of a human subject. It has been settled that the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above. That Applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the

same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. Thus, the method the '177 PGPub discloses is same as the method of the instant claims. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps, i.e., administering the same compound in the same amount to the same or similar patient population, are already known even though applicant has proposed or claimed the mechanism (e.g., by increasing the expression of keratinoctye growth factor (FGF-7) in hair follicle cells). Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Therefore, by practicing the process disclosed in the '177 PGPub one would inherently be practicing the instantly claimed process, anticipating instant claims 1-4, 11 and 12.

Regarding prior art rejection of claims 1 and 4 rejected as indefinite, see MPEP 2173.06.

Claims 1-4, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwarz (US Patent 2,960,442, issued 15 Nov 1960, cited in PTO-892).

Schawrz discloses a hair dressing preparation, or external skin preparation, containing the nucleic acid adenoside (column 2, lines 16 and 52-58). Schwarz discloses the preparation applied to tonsorial hair, or hair on the head including the scalp to impart a natural well groomed appearance (column 1, lines 63-65). By applying said preparation to the head, one inherently treats hair follicle cells that are dermal papilla cells or outer root sheath cells, anticipating instant claims 11 and 12. Schawrz does not explicitly state that the biological pathway by which the disclosed method operates is by increasing the expression of keratinoctye growth factor (FGF-7) in hair follicle cells.

Note that "increasing the expression of keratinoctye growth factor (FGF-7) in hair follicle cells" is merely considered to be a new function or the unknown property or mechanism of action of a known treatment, applying said hair dressing preparation to the head. It has been settled that the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above. That Applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the

same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. Thus, the method Schawrz discloses is same as the method of the instant claims. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps, i.e., administering the same compound in the same amount to the same or similar patient population, are already known even though applicant has proposed or claimed the mechanism (e.g., by increasing the expression of keratinoctye growth factor (FGF-7) in hair follicle cells). Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Therefore, by practicing the process disclosed by Schawrz one would inherently be practicing the instantly claimed process, anticipating instant claims 1-4, 11 and 12.

Regarding prior art rejection of claims 1 and 4 rejected as indefinite, see MPEP 2173.06.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 11 and 12 are rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 7,182,939, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Tajima et al., US Patent Application Publication US 2002/0192177, is the Pre-Grant Publication of Application 10/113,940, since issued as U. S. Patent No. 7,182,939. As recited above, the '177 PGPub anticipates the instantly claimed process. Claim 1 of U. S. Patent No. 7,182,939, drawn to the process

disclosed in the '177 PGPub, therefore claims common subject matter to instant claims 1-4, 11 and 12.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1-4, 11 and 12 are provisionally rejected on the ground of nonstatutory double patenting over claim 4 of copending Application No. 11/655,134. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claim 4 of copending Application No. 11/655,134 recites, "A method of preventing hair loss comprising applying, to scalp or hair roots, a composition containing, as an active ingredient, adenosine and a carrier therefore." Instant claim 4 is drawn to a method for maintaining and promoting hair thickening comprising applying to the scalp an external skin preparation containing adenosine. As recited above, applying to the scalp as recited in claim 4 of copending Application No. 11/655,134 inherently addresses the limitations of instant claims 11 and 12.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1/28/08

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